IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This document relates to: *All Actions*	MDL No. 19-2875 (RBK)

ORDER NO. __

THIS MATTER having been opened to the Court by Plaintiffs for entry of an order granting their motions in limine, and the Court having considered the submissions of the Parties, and for good cause shown:

It is hereby ORDERED this ___ day of _____, 2024 that Plaintiffs' motions in limine are GRANTED:

1. Defendants cannot assert that it is not appropriate to perform a retrospective analysis of their conduct or the consequences, including for example the resulting adulteration of the contaminated API and VCDs.

2. Defendants cannot defend their conduct by pointing to lack of knowledge or action by the FDA prior to ZHP's disclosure of the contamination in June 2018, or blame or point the finger at the FDA in any way as a defense or excuse for their conduct.

3. Defendants cannot blame third-parties, including prescribing physicians, the FDA, or others, for the damages at issue.

4. Defendants cannot assert that the FDA statement advising patients not to

discontinue their use of the VCDs until they could obtain a prescription for a replacement medication or treatment meant that the FDA did not believe that there was an unacceptable health risk due to the contamination of the VCDs.

5. The FDA information statements regarding the valsartan and other sartans' contamination should not be referenced, or used to defend or deflect liability. For example, ZHP cannot assert that they excuse ZHP's violations of cGMPS since one of the statements explicitly notes ZHP's violations and the Warning Letter, and they do not excuse the sale of the contaminated VCDs, all of which were recalled due to the contamination.

6. Defendants cannot assert that there was an industry-wide problem, or that industry standards did not require them to identify and control all genotoxic impurities from their manufacturing processes.

7. ZHP Defendants cannot disclose or rely on hearsay discussions with Jinsheng Lin, Ph.D, or other sources, to assert translation or interpretation of the July 27, 2017 email that differs from 30(b)(6) testimony of Min Li, or ZHP's translation.

8. Defendants cannot assert or argue that NDMA and NDEA are not, and were not known to be at all relevant times, genotoxic, probable human carcinogens.

9. General causation is not an element of the claims at issue, and is not an issue to be determined at trial.

10. Defendants cannot reference or assert the Valisure Citizen Petition, in any way, including but not limited to with regard to Dr. Najafi, nor can they use the Valisure Citizen Petition to assert that brand diovan contained NDMA or NDEA.

11. Defendants cannot argue that the specifications for the valsartan API and VCD's permitted the NDMA and NDEA contamination/that the specifications did not prohibit the NDMA and NDEA contamination.

12. Defendants cannot argue that their VCDs were not adulterated because they complied with the USP monograph for valsartan.

13. Defendants cannot argue "all drugs have impurities."

14. Defendants cannot refer to the "alleged" presence of "purported impurities" or similar language, or dispute that all of the at-issue valsartan was contaminated, including untested lots (if any) at levels above the limits set by the FDA.

15. Defendants filed no cross-claims for contribution/indemnification, and disclosed no experts to do so, and should be precluded from asserting evidence or making arguments consistent therewith, including that a co-defendant was at fault, or liable for Plaintiffs' damages.

16. Defendants cannot assert the cost of replacement drugs or therapies.

17. Defendants cannot assert that the contaminated VCD's had value based on their efficacy.

18. Defendants cannot reference, assert, or rely on opinions of defense experts that rely on the precluded opinions of other defense experts. For example, Dr. Afnan's opinions that rely on Dr. Xue's precluded opinions.

19. Defendants cannot argue that the relevant warranties only went to the prescribers.

20. Defendants cannot argue they are good companies, the "societal benefits" of their VCDs and other products, or the cost of drug research and development.

21. Defendants cannot postulate a "but-for" world in which the contamination was disclosed earlier and the contaminated API and VCDs would have remained available for purchase.

22. Defendants cannot reference double or treble damages, attorney fees, statutory penalties, pre- or post-judgment interest.

23. Defendants cannot argue they complied with SOPs, guidances, or regulations without specifically identifying same; and specifically-referenced SOPs must have been produced in discovery.

24. Defendants cannot refer to their API or VCDs as "life saving" or similar descriptions.

25. Defendants cannot assert or argue that the prescription of VCDs was standard

of care.

26. ZHP Defendants cannot assert any evidence or argument inconsistent with their filed stipulations.

27. Defendants cannot argue that Teva's and Torrent's VCDs were not adulterated because the FDA did not issue Warning Letters to them.

28. Defendants cannot argue that they complied with cGMPs' in the manufacture of the API and VCDs.

29. Defendants cannot argue that the contaminated API and VCDs were not adulterated.

30. Defendants cannot argue that the contamination was unavoidable or unforeseeable.

31. Defendants cannot argue that Teva's and Torrent's VCDs were not adulterated because the FDA never declared their VCDs did not meet USP standards or never de-listed the VCDs from the Orange Book.

32. Teva and Torrent cannot argue that they were not responsible for the quality of the API incorporated into their finished dose VCDs.

33. Defendants cannot raise the notice issues raised on the dispositive motions at trial.

34. Defendants cannot assert irrelevant, confusing, misleading, or unduly prejudicial background facts about MSP or its assignors, including but not limited to:

    a. The Litigation Between Life Wallet and Cano Health ("Cano"),

    b. Reported Investigations by the S.E.C. and United States Attorney's Office for the Southern District of Florida into Life Wallet,

    c. MSP's Business Model,

    d. LifeWallet's Financial Condition, and

e. Issues Related to MSP's Assignors; and

f. Defendants Cannot Argue that MSP Is Merely an Assignee of SummaCare and Emblem and That It Is Not a Health Plan That Paid for Valsartan.

35. Defendants cannot argue or suggest that TPP Trial Subclass Plaintiffs/Members will retain any benefit and not pass it along to their insureds.

36. Defendants cannot argue Medicare Part D Offsets (collateral source; reconciliation process).

37. Defendants' cannot suggest that there should be set offs for unquantified, speculative subsidies and reimbursements.

38. Defendants cannot reference the dollar amounts for which they sold the API and VCDs, and the amounts of the reimbursements requested and/or agreed to with regard to downstream customers.

39. Defendants cannot disparage the insurance industry.

40. The Court should not permit Defendants to discuss how a verdict would economically affect either Defendants or society. This sort of conjecture is non-probative, prejudicial, and should be excluded.

41. Defendants cannot argue TPP Trial Subclass Plaintiffs/Members are "sophisticated users" (see affirmative defense).

42. Defense counsel should be barred from suggesting that they are one in the same as Defendants by using the terms "we," "us," and/or "our" when referring to Defendants. Such statements are irrelevant, inaccurate, and prejudicial.

43. Defendants cannot criticize plaintiff attorneys, plaintiffs for bringing lawsuits, or reference attorney advertising.

44. The manner in which Plaintiff learned about this litigation or their attorneys, and when or why they retained their attorneys to represent them, is irrelevant and unrelated to Plaintiff's claims and subject to attorney-client privilege.

45. Defendants cannot inject arguments regarding the consumers' damages or suggest consumers' benefitted.

46. Defendants cannot seek sympathy for big corporations targeted in litigation, or assert that they employ people in New Jersey.

/s/
Hon. Robert B. Kugler, U.S.D.J.